Attorney Docket No. 84566/HG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TO NO. 1-703-308-6916

TOTAL PAGES: 5
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Attorney: HERBERT GOODMAN

Dated: August 20, 1997

Applicant(s)	:	Sankyo Co., Ltd.
U.S. Patent No.	:	4,572,912
Issue Date	:	February 25, 1986
Application Serial No.	:	06/644,996
Application Filing Date	:	August 28, 1984
Inventors	:	Takao YOSHIOKA, Eiici KITAZAWA, Tomoyuki KURUMADA, Mitsuo YAMAZAKI and Kazuo HASEGAWA
For	:	THIAZOLIDINE DERIVATIVES, THEIR PREPARATION AND COMPOSITIONS CONTAINING THEM
Attorneys for Applicant	:	Frishauf, Holtz, Goodman, Langer & Chick, P.C.

SECOND SUPPLEMENT TO APPLICATION FOR EXTENSION OF PATENT TERM UNDER 36 USC 156

BOX PATENT EXTENSION
Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

ATTENTION: Ms. Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner for Patent Policy and Projects

This serves to supplement the APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 USC 156, filed February 27, 1997.

Following the request of Ms. Karin Tyson during a telephone interview on August 19, 1997, enclosed is a copy of a letter from

Dr. Solomon Sobel of the FDA dated August 4, 1997 which sets forth approval for new indications for troglitazone (PRELAY™ and REZULIN™), namely the monotherapy use of troglitazone for type II diabetes and the use of troglitazone in combination with sulfonylureas in the treatment of type II diabetes.

Respectfully submitted,

HERBERT GOODMAN
Reg. No. 17,081

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HG/ac

Enclosure: Copy of letter dated August 4, 1997 from the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service From: BARTH

Food and Drug Administration
Rockville MD 20857

AUG 4 1997

NDA 20-720/S-002
NDA 20-720/S-003
NDA 20-720/S-005

Parke Davis Pharmaceutical Research
Attention: Mary E. Taylor, M.P.H.
Director, Worldwide Regulatory Affairs
P.O. Box 1047
Ann Arbor, MI 48106-1047

Dear Ms. Taylor:

Please refer to your supplemental new drug applications dated February 3, 1997 (S-002), February 14, 1997 (S-003), and June 17, 1997 (S-005), received February 4 and 18, and June 19, 1997, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rezulin™ (troglitazone) Tablets, 200 mg and 400 mg.

We acknowledge receipt of your submissions to S-002 and S-003 dated February 14 and 20, March 14, April 3, 14, 16, and 29, May 5, 14, 16, 23, and 28, June 4, 11, and 20, and July 2 and 29, 1997. We also acknowledge the submission to S-005 dated July 8, 1997. The User Fee goal dates for these application are February 4, 1998 (S-002), February 18, 1998 (S-003), and December 19, 1997 (S-005), respectively.

These supplemental applications provide for:

1. S-002 adds the use of Rezulin™ in combination with sulfonylureas in the treatment of type II diabetes (new indication);

2. S-003 adds the use of Rezulin™ as monotherapy in type II diabetes (new indication);

3. S-005 adds a new 300 mg tablet dosage form (new strength).

We have completed the review of these supplemental applications, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submissions dated July 8, 1997 (container labels for 300 mg tablets in bottles of 60 and 120 and blister packages) and July 29, 1997 (package insert.) Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on July 8 (300 mg container and blister labels) and July 29 (package insert), 1997.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days

after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING for approved supplemental NDA 20-720/S-002, S-003, S-005." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you of your Phase 4 commitment dated July 29, 1997, to conduct a clinical study to determine the safety of Renilin use in patients with renal disease. A draft protocol, including the study length and number of patients to be studied, will be submitted to the FDA for approval within three months of the approval of this NDA.

The protocol, data, and final report should be submitted to your IND for this product and a copy of each cover letter sent to this NDA. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of the commitment. The status summary should include the number of patients entered, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments should be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Michael F. Johnston, R.Ph., Consumer Safety Officer, at (301) 443-3490.

Sincerely yours,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research